IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ROXANE LABORATORIES, INC., Plaintiff	:	
	:	CIVIL ACTION
v.	:	
	:	NO. 09-CV-1638
SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, Defendant	:	

January _26__, 2010 **Anita B. Brody, J.**

MEMORANDUM

I. INTRODUCTION

On July 9, 2009, Plaintiff Roxane Laboratories, Inc. ("Roxane") filed an Amended Complaint alleging antitrust violations against Defendant SmithKline Beecham Corporation, doing business as GlaxoSmithKline, Inc. ("GSK").

GSK manufactures and sells Flonase Nasal Spray ("Flonase"), a brand name version of fluticasone propionate, used to treat asthma and allergies. Roxane markets a variety of generic drugs, including fluticasone propionate nasal spray ("generic Flonase"). Roxane alleges that GSK filed a series of sham citizen petitions with the Food and Drug Administration ("FDA") to delay the entry of their generic Flonase into the market. Plaintiff brings this action under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover damages for alleged violations of Section 2 of the Sherman Act, 15 U.S.C. § 2. On July 23, 2009, GSK filed a Motion to Dismiss the Amended

Complaint.

II. BACKGROUND[1]

Under the Federal Food, Drug and Cosmetic Act ("FDCA"), drug manufacturers must receive FDA approval before selling a new drug. When the manufacturer of a new drug obtains FDA approval, it enjoys a period of market exclusivity during which its patent is protected. Once this period expires, other ("generic") manufacturers may market and sell the drug. Before the generic version is approved for sale, a prospective manufacturer of a generic drug must file an Abbreviated New Drug Application ("ANDA") with the FDA. The manufacturer must demonstrate to the FDA that the generic version is the "bioequivalent" of the brand name drug; in other words, the generic version must contain the same active ingredient(s), dosage form, route of administration, and strength. Once a generic drug enters the market, the price and sales volume of the name-brand drug typically drop. The existing ANDA framework, commonly known as the Hatch-Waxman Act, facilitates market entry for generic medications and is intended in part to increase the availability of low-cost generic drugs.

While the approval of a generic drug is pending, "citizen petitions" may be filed with the FDA to express legitimate concerns regarding a product and to request that the FDA take, or refrain from taking, administrative action. Because citizen petitions can delay a generic drug's approval, they are open to abuse by pharmaceutical companies attempting to prolong their monopoly in the market.[2]

---

[1] All facts were considered in the light most favorable to Plaintiff, the non-moving party.

[2] In 2007, after the citizen petitions in this case were filed, Congress passed a law that allows the FDA to dismiss citizen petitions summarily in order to prevent pharmaceutical companies from using this process to unlawfully extend their monopolies. *See* 21 U.S.C. §

Plaintiff contends that in 2004, as the end of GSK's exclusivity period for Flonase approached, GSK filed a series of sham citizen petitions and related documents solely to delay the FDA's approval of Roxane's generic version of the drug, and with no reasonable basis for objecting to the approval. Plaintiff alleges that because of this unlawful behavior, approval of its generic Flonase was delayed for close to two years. Roxane asserts that it believed the FDA was likely to approve its ANDA in or near May 2004, but that in fact the FDA failed to approve the ANDA until February 22, 2006.

III. JURISDICTION

Jurisdiction over this action is proper under 28 U.S.C. §§ 1331 and 1337(a), and Section 4 of the Clayton Act, 15 U.S.C. § 15.

IV. LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(6), a court must grant a motion to dismiss if the plaintiff fails "to state a claim upon which relief can be granted." In deciding a motion to dismiss pursuant to Rule 12(b)(6), the court must accept as true the well-pleaded allegations of the complaint and draw all reasonable inferences in the plaintiff's favor. *Brown v. Card Serv. Ctr.*, 464 F.3d 450, 452 (3d Cir. 2006). While a complaint "does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal quotation marks omitted). To survive a motion to dismiss, a complaint must contain "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial

---

355(q).

plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (internal quotation marks omitted).

V. DISCUSSION

Defendant argues that Plaintiff lacks antitrust standing under applicable antitrust law. A private antitrust plaintiff must demonstrate antitrust standing by establishing a right to a remedy under the Clayton Act. *See Out Front Prods., Inc. v. Magid*, 748 F.2d 166, 168-69 (3d Cir. 1984); *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 534-35 (1983).

Section 4 of the Clayton Act provides that a private person "injured in his business or property by reason of anything forbidden in the antitrust laws . . . shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee." 15 U.S.C. § 15(a). The Clayton Act includes the Sherman Act as one of the antitrust laws. *See* 15 U.S.C. § 12. The Supreme Court has stated that "despite the broad wording of § 4 there is a point beyond which the wrongdoer should not be held liable. . . . It is reasonable to assume that Congress did not intend to allow every person tangentially affected by an antitrust violation to maintain an action to recover threefold damages for the injury to his business or property." *Associated Gen. Contractors of Cal.*, 459 U.S. at 534-35 (internal citations omitted).

Whether a defendant may be held liable for a plaintiff's injury requires courts "to evaluate the plaintiff's harm, the alleged wrongdoing by the defendants,

and the relationship between them." *Id.* at 535. This inquiry is a component of antitrust standing. *See id.* at 535 n.31.

As part of showing antitrust standing, a private plaintiff must demonstrate injury-in-fact or causation; in other words, that the defendant's alleged unlawful conduct was a "material cause of injury to its business or property." *See Out Front*, 748 F.2d at 169; *see also Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 806 (D.C. Cir. 2001). Plaintiff must show proof of *some* damage resulting from the unlawful behavior; a plaintiff "need not exhaust all possible alternative sources of injury." *Out Front*, 748 F.2d at 169; *see Andrx*, 256 F.3d at 806.

A plaintiff who was a "potential" competitor during the time of the alleged unlawful behavior—in other words, a competitor who had not yet entered the market—must demonstrate intention and preparedness to enter the market in order to show injury. *See Out Front*, 748 F.2d at 170 (plaintiff should show it was "poised and ready to enter the market"); *Andrx*, 256 F.3d at 185 ("[C]ourts require a 'potential' competitor to demonstrate both its intention to enter the market and its preparedness to do so."). If a plaintiff cannot show it was ready to enter the market, "there is unlikely to be any plausible evidence to show that defendants impeded this effort." *Out Front*, 256 F.3d at 170. If a plaintiff was unprepared to enter the market, then the defendant's behavior was not a but-for cause of plaintiff's inability to enter the market.

To demonstrate intention and preparedness, a plaintiff "must show not

only that it had the background, experience and financial ability to make a viable entrance, but even more important, that it took affirmative actions to pursue the new line of business." *Out Front*, 748 F.2d at 170. *See also Andrx*, 256 F.3d at 186 ("Indicia of preparedness include adequate background and experience in the new field, sufficient financial capability to enter it, and the taking of actual and substantial affirmative steps toward entry, such as the consummation of relevant contracts and procurement of necessary facilities and equipment.") (internal quotation marks omitted).

Andrx, like this case, involved potential generic manufacturers of a name brand drug. Reading *Andrx* most favorably to Defendant, the D.C. Circuit required that a potential generic manufacturer of a drug, in order to show intention and preparedness to enter the market, allege either (1) that FDA approval of its drug was probable at the relevant time, or (2) that the claimant anticipated that FDA approval was probable. *See Andrx*, 256 F.3d at 186-87 (stating that "Biovail did not explicitly allege that . . . it anticipated FDA approval," and "Biovail could have alleged its intent and preparedness to enter the market by claiming that FDA approval was probable.").

Defendant relies on this language in *Andrx* to argue that Roxane, in order to withstand this Motion to Dismiss, must have alleged in its Amended Complaint that FDA approval was probable, and that alleging that it "believed" or "anticipated" that FDA approval was probable is insufficient. This argument is unpersuasive for several reasons. First, *Andrx*, while persuasive, does not bind me,

and the Third Circuit has never required that a plaintiff allege that FDA approval was probable.

Second, Defendant overreads the *Andrx* case. First, the *Andrx* court does not declare that a specific allegation regarding probability of FDA approval is an absolute requirement of the intent and preparedness standard. Rather, it considers FDA approval as an important factor in determining a potential competitor's intent and preparedness to enter the market. The court states that Biovail "*could have alleged* its intent and preparedness to enter the market by claiming that FDA approval was probable," *id.* at 187 (emphasis added), and that "Biovail did not explicitly allege *that it was prepared* to bring a generic version . . . to market *or* that it anticipated FDA approval." *Id.* at 186 (emphasis added). These statements illustrate what would have been appropriate allegations. Second, even if the court's purpose was to require any potential competitor to make an allegation regarding the probability of FDA approval, the court used at least two different formulations—a subjective and an objective version—to address allegations of FDA approval, and either would be sufficient. Initially, the court indicated that Biovail should have alleged that "it *anticipated* FDA approval." *Id.* at 186 (emphasis added). Next, the court stated that Biovail could have alleged that "FDA approval *was* probable." *Id.* at 187 (emphasis added). The former statement seeks a subjective allegation indicating that the plaintiff believed that FDA approval was likely or probable. The latter statement calls for a more objective allegation. Thus, either allegation would satisfy *Andrx*.

I choose to consider the probability of FDA approval as one significant factor to recognize within the intent and preparedness standard.[3] I therefore decline to dismiss Plaintiff's Amended Complaint solely because Plaintiff alleged that it "believed that the FDA was likely to approve" its ANDA at a certain date (Compl. 6), rather than alleging that "FDA approval was probable."

Plaintiff Roxane's allegations are sufficient to demonstrate both an intention and preparedness to enter the market.[4] Roxane's allegations demonstrate that it had the background, experience and financial ability to market and sell generic Flonase in May 2004. Roxane is a longstanding generic drug manufacturer with over 20 years of experience marketing generic drugs in the United States. It had manufacturing and distribution networks in place at the relevant time, and possessed a familiarity with the FDA approval process. Further, Roxane took affirmative actions to enter the market for Flonase. Roxane submitted an ANDA in October 2002, over one and a half years before GSK's exclusivity period expired. Additionally, in May 2004, Roxane manufactured approximately four million units of generic Flonase in anticipation of market approval. Finally,

---

[3] Even if I adopted a requirement that a plaintiff must make some allegations regarding the probability of FDA approval, alleging an anticipation or belief that FDA approval was probable would be sufficient to satisfy this standard. In reality, there is little substantive difference between a plaintiff generic manufacturer alleging in a complaint that FDA approval was probable versus alleging that it anticipated that FDA approval was probable. Further, a claimant can sufficiently show intention and preparedness to enter a market with an allegation that is framed subjectively, assuming such a belief is accompanied by other factual allegations which in fact show intent and preparedness.

[4] Allegations are read in the light most favorable to the Plaintiff.

Roxane alleged that it reasonably believed that FDA approval was probable in approximately May 2004, and that it intended to enter the market at this time.

Defendant also argues that a letter from the FDA to Roxane which rejects Roxane's ANDA as "Not Approvable" in March 2005 should be judicially noticed, and is evidence that refutes Plaintiff's allegations of intention and preparedness, including that FDA approval was probable in May 2004. This argument is without merit. Even assuming that the letter is judicially noticeable, it fails to negate Roxane's allegations of antitrust injury-in-fact. GSK essentially argues that the letter shows that FDA approval was precluded before March 2005, and thus refutes Roxane's allegations that injury began in May 2004. Implicit in this argument is the notion that the letter would have been sent regardless of GSK's actions. There is no way for me to make such a determination at this stage of the litigation. GSK's actions may well have played a role in the FDA's decision to send the "Not Approvable" letter. In fact, such a scenario conforms with Roxane's allegations that GSK's actions played a role in the FDA approval process. The letter in March 2005 is hardly surprising, since Plaintiff admits that the FDA did not approve Roxane's ANDA until 2006. Further, GSK's actions clearly predated the March 2005 "Not Approvable" letter.

For these reasons, Roxane has sufficiently alleged antitrust standing.

VI. CONCLUSION

Defendant's Motion to Dismiss Plaintiff's Amended Complaint is DENIED.

s/Anita B. Brody

_____

ANITA B. BRODY, J.

Copies **VIA ECF** on _____ to:

Copies **MAILED** on _____ to: